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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P200201137 WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 03/00572	International filing date (<i>day/month/year</i>) 02.09.2003	Priority date (<i>day/month/year</i>) 02.09.2002
International Patent Classification (IPC) or both national classification and IPC A61M39/08		
Applicant UNOMEDICAL AS et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 11 sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 01.04.2004	Date of completion of this report 22.09.2004
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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/DK 03/00572**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

3, 8 as originally filed
1, 2, 2a, 4-7, 9 received on 03.04.2004 with letter of 01.04.2004

Claims, Numbers

1-12 filed with telefax on 18.08.2004

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55:2 and/or 55:3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☒ the claims, Nos.: 13-14
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 11-12

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 11-12 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-10
	No: Claims	
Inventive step (IS)	Yes: Claims	1-10
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	

2. Citations and explanations

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see separate sheet

Section III.

1. Claims 11 and 12 do not fulfil the requirements of Article 6 PCT, when taken in combination with PCT Guidelines chapter III-4.8a, since the use is not unambiguously clearly defined. Merely one intended use is indicated.

Section V.

1. The closest prior art is represented by document WO-A-02/46080 (=D1) which discloses an apparatus for adjustment of the length of an infusion tubing as defined in the preamble of claim 1.
 - 1.1 Claim 1 therefore fulfils the requirements of Article 33(2) PCT.
2. The subject-matter of claim 1 differs therefrom in the definitions of a partition plate, a cylinder part and a circular wheel. These means enables an improvement over D1 in that one end is adjustable in its length, for a certain length, independently of the other end.

In D1 the problem is that both tube ends will wound or unwound simultaneously.

 - 2.1 Claim 1 therefore fulfils the requirements of Article 33(2) PCT.
 - 2.2 Claim 1 is a combination of originally filed claims 1 and 5.
 - 2.3 Claims 2-7 are dependent on claim 1.
3. Claim 8 defines a method of adjusting the tube length of a tube by means of an apparatus having the essential features of the apparatus of claim 1.
 - 3.1 Claims 9-10 are dependent on claim 8.
4. Claims 1-10 do therefore fulfil the requirements of Article 33(2)-(4) PCT.

An apparatus and a method for adjustment of the length of an infusion tubing

5 The invention relates to an apparatus/a medical utensil for adjustment of the length of an infusion tubing, comprising a housing with an axle/cylinder part arranged around a central axis, said housing further comprising at least one turnable unit.

10 The invention also relates to a method for adjustment of the length of an infusion tubing by means of an apparatus comprising a housing with an axle/cylinder part arranged around a central axis, said housing further comprising at least one turnable unit.

15 When infusion kits are used in combination with an insulin pump it is necessary to use a tubular element of a certain length, since the distance between the insulin pump and the cannula housing will vary. This variation in the distance between pump and cannula occurs [ie] during the night when the pump sits on the nightstand. In that case the tubing may be used in its full length. When, during the daytime, the pump is arranged in the belt of the diabetic, the requisite tubing length will be shorter – but still variable, since the cannula may be inserted in different places in the body.

25 Therefore the problem of excessive tubing may occur that the user may find difficult to arrange/conceal. That means that when cannula housing is arranged in the immediate vicinity of the pump and the user simultaneously uses a long tubing of 110 cm, a worst case scenario will involve about 90 cm that are not "in use".

30 It is desired to develop a winding device that is able to compensate for the above-described problem.

The winding device is typically located close to the skin — underneath the clothes. Optionally by means of a clip to the trouser waistband.

5 The winding device must not be able to cause failures of any kind in the supply of insulin; neither by damage to/deformation of tubing nor in any other way.

10 WO 96/35472 teaches an apparatus of the kind described above; it describes a portable medical pump wherein a winding unit is integrated for the infusion tubing. The drawback of this system is that, apart from the tubing constituting an integral part of the pump device, such system is mechanically complex and restricts the place where the winding may occur to a place near the infusion part and not anywhere on the tubing nor on just any tubing; the winding system being designed exclusively for the pump of which it is an
15 integral part. To the user the system is not particularly flexible, since it is not possible to locate the pump unit and the winding unit apart. Therefore the unit will be very visible to the user when he wears the pump unit.

20 WO 02/46080 teaches an apparatus as stated in the preamble. This apparatus, however, has the disadvantage that both tube ends will be wound or unwound simultaneously at the same time.

25 It is thus the object of the present invention to provide an apparatus wherein the above-referenced drawbacks are overcome, and whereby it is possible to perform a winding of an infusion tubing to adjust the connecting length between pump and the infusion site, the apparatus being independent of infusion cannula and pump. Thus the apparatus enables reuse due to said independence. The system also makes it possible for the user to locate the winding unit anywhere on the body he finds suitable with regard to physiology
30 and with regard to clothing. It is thus an option to arrange it underneath one's sweater, in one's waistband, pocket or the like.

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Moreover, an automatic winder is obtained and wherein length increases and reductions are accomplished in a simple manner. The structure is also suitable for the handicapped and, likewise, it is a time-saving device for use

tubing wound around the rotatable winder wheel will be extending in the opposite direction. The free end of the tubing is subsequently led out through the housing. The tubing length is distributed such that there are equal lengths of tubing wound on the fixed winder wheel and the rotating winder wheel, respectively.

When a pull is thus exerted at the end of the tubing that is in direct communication with the rotating winder wheel, the following occurs:

- 10 The tubing is unwound from the rotating wheel and thus constitutes the extension. The rotating wheel turns on the axle due to the pull that is exerted on the tubing, and due to the internal construction tubing will be conveyed from the lower fixed winder wheel to the rotating wheel. The construction of the individual elements means that the transfer from the one wheel to the other will constitute a length of tubing, whose length is half that unwound from the winder.

Finally, it is an option to let a part of the interior, corresponding to the part designated the partition plate, be spring-biased such that it is possible to have the tubing pulled into the apparatus/winder.

By providing an apparatus according to the invention and as further featured in claim [X] it is accomplished that only the one end of the tubing can be pulled out of the housing. The term 'stationary' as used in this context is intended to designate 'non-turnable' and 'immovable'.

By providing an apparatus according to the invention and as further featured in claim [3] it is accomplished that both ends of the tubing can be pulled out of the housing.

[] 5 By providing an apparatus according to the invention and as further featured in claims 4-6 an expedient embodiment of the apparatus is accomplished.

5 By providing an apparatus according to the invention and as further featured in claim 7 it is an option to automatically pull the tubing back into the housing again.

10 By providing an apparatus according to the invention and as further featured in claim 8 convenient exchange is accomplished between the two cylinder parts.

[] 9 The invention also relates to a method as featured in claims 11-12.

15 Finally the invention also relates to use of the apparatus as recited in claims 13 and 14.

The invention will now be explained in further detail with reference to the drawing, wherein:

20 Figure 1 is an exploded view of an apparatus according to the invention containing the individual elements;

Figure 2 shows the apparatus shown in Figure 1, but wherein the location of the tubing in relation to the individual constituent components is indicated;

25

Figure 3 shows an apparatus according to the invention, seen in a perspective view.

30 Figure 1 shows an apparatus 1 in an exploded view, with a housing 3 and comprising an upper part 16 and a lower part 17. Both the upper and the lower parts are circularly configured pieces, wherein the lower part is plate-

shaped. Coaxially on this plate, an axle/cylinder part 4 is arranged, in this case also designated fixed winder wheel/stationary axle, about which a part of an infusion tubing 2 can be wound. It is noted that the cylinder part 4 can be turnable and/or it can be locked by means of eg a manually operated lock.

5 In this embodiment, the cylinder part 4, however, is not turnable. In parallel with the axis and coincident therewith, a first axle 9 extends, and on said first axle 9 a first plate 10, also designate the partition plate, is arranged. Thus, the partition plate 10 has a through-going bore, through which the axle 9 extends. In the periphery of the partition plate 10, a rectangular slit is
10 provided, in which a circular plate is secured, also designated return wheel 12, the diameter of which is considerably less than the diameter of the partition plate and about one third thereof, and wherein the outer periphery of said return wheel is flush with the periphery of the partition plate or is located within same.

15

Laterally to said return wheels, recesses 13 are shown that are configured to be so wide that the tubing is able to travel therethrough. In parallel with the axis of said partition plate and above there is arranged a rotating winder wheel/turnable wheel 11, that also comprises a through-going central bore
20 that encircles the first axle 9.

20

This winder wheel is rotatable and, besides, the partition plate is also turnable about the axle 9. The rotatable winder wheel and the partition plate 10 constitute the turnable unit 6. The tubing is also wound around the rotating
25 winder wheel, from which an end part extends. Finally the housing ends at the top in an upper part 16 configured as a partially cylindrical dish that encircles [the] turnable unit 6 and ends close to the lower part 17 of the housing.

[] 2

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Figure 2 is identical to Figure 1, but the tubing 2 is shown herein in its mounted state. As will appear, the tubing 2 extends into the housing in one

direction and is wound around the fixed winder wheel, eg counter-clockwise. From here the tubing proceeds up through the recess 13 and is wound around the return wheel, following which the tubing is conveyed around rotating winder wheel 11, where this winding extends opposite the winding of the fixed winder wheel, ie clockwise. From here the tubing exits]

[the
housing 3

5

The functioning of the apparatus 1 is that the tubing 2 is conveyed into the winder such that a short length of the tubing 2 allows coupling to eg a pump. About half of the tubing, designated the first length of tubing 5, is wound around the fixed winder wheel 4. The tubing is subsequently conveyed around the return wheel 12. The return wheel is mounted on the plate 10 that separates the fixed and the rotating winder wheel. The return wheel ensures that the tubing is wound onto the rotating winder wheel 11 and the fixed winder wheel 4 in [each their] direction, ie clockwise/counter-clockwise. Simultaneously the return wheel 12 conveys the tubing 2 past the partition plate 10, such that the tubing 2 is conveyed from the fixed winder wheel 4 to the rotating winder wheel 11. The remainder of the tubing and designated the second length of tubing 18 is wound onto the rotating winder wheel 11. There are equal amounts of tubing wound on the two winder wheels in this

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[] opposite

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example. When extension of the tubing is to be accomplished, the following occurs: the tubing 2 is unwound from the rotating wheel 11 by a pull in the length of tubing 7. The rotating wheel 11 turns about the axle 9, whereby the return wheel 12 will be forced to follow. Since, via the partition plate 10, the return wheel 12 rotates about the central axle 9, tubing will be transferred from the fixed to the rotating wheel.

25

Likewise, the return wheel 12 moves half the distance of the length of tubing unwound. This transfer will constitute a length of tubing, whose length is half that of the section that is unwound from the winder. Since the return wheel 12 is relieved the rotating winder wheel 11 by twice half of the length of the unwound length of tubing, the requisite length of tubing is accomplished that

Y by
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from the fixed winder wheel 4 to the rotatable winding wheel 11

A spring configured in such a manner that it seeks to rotate the partition plate in that direction, whereby the tubing is tightened;

A rotating winder wheel mounted on the central axle.

- 5 Thus Figure 2 does not show the spring, but as mentioned it is located on the partition plate 10 and secured to the inner faces of the housing, whereby it is possible to tighten the tubing.

Finally Figure 3 provides a perspective view of the apparatus, wherein it comprises a housing 3 with a tubing 2, from where a first end part and a second end part 7, 8 will appear that protrude from the first and second tubing branches 14, 15, respectively. Expediently the two exits for the first end part and the second end part, respectively, are situated diametrically opposite each other. The one end part can be extended, while the second end part has a stationary distance to the housing, or conversely.

Besides, it should be noted that the apparatus can be configured such that both ends [on] the tubing can be pulled outwards. That is, the axle 4 and the turnable wheel 11 can both be turnable. Both units [can also be made non-] turnable by means of a lock. In this manner the patient himself is able to regulate which of the two units [is to be turnable and hence which of the tubing ends is to be adjustable in length, including optionally both ends.

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Claims

1. An apparatus/a medical utensil (1) for adjustment of the length of an infusion tubing (2), comprising a housing (3) with an axle/cylinder part (4) arranged about a centre axis, said housing (3) further comprising at least one turnable unit (6) and a first axle (9), the centre axis of which coincides with the centre axis of the axle (4), and about which axle (9) the turnable unit (6) turns, characterised in that the turnable unit (6) comprises a turnable first plate – partition plate 10 – which is turnable about the first axle (9) and a wheel/cylinder part (11) turnable about the same axle (9); and in that, at its periphery, the partition plate (10) comprises a circular plate/wheel – return wheel (12) – around the periphery of which lengths of the tubing abut.
2. An apparatus according to claim 1, characterised in that, said axle/cylinder part (4) and wheel/cylinder part (11) are rotatable relative to each other.
3. An apparatus according to claim 1 or 2, characterised in that the axle (4) is a stationary axle.
4. An apparatus according to claim 1 or 2, characterised in that the axle (4) is a turnable axle.
5. An apparatus according to any one of the preceding claims, characterised in that the return wheel (12) is turnable about an axle mounted on the partition plate.
6. An apparatus according to any one of the preceding claims, characterised in that the apparatus comprises a spring, said spring being connected to the partition plate (10) and to a part which is stationary within the housing (3), preferably the walls of the housing (3).

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7. An apparatus according to any one of the preceding claims, **characterised in** that the diameter of the axle/the cylinder part (4) and the turnable cylinder part (11) are essentially identical.

5

8. A method for adjustment of the length of an infusion tubing (2) by means of an apparatus comprising a housing (3) with an axle/cylinder part (4) arranged about a centre axis, said housing (3) further comprising at least one turnable unit (6) and a first axle (9), the centre axis of which coincides with the centre axis of the axle (4), and about which axle (9) the turnable unit (6) turns, said
10 turnable unit (6) comprising a turnable first plate – partition plate 10 – which is turnable about first axle (9) and a wheel/cylinder part (11) turnable about the same axle (9), **characterised in** that a first length of tubing is wound around the axle (4); that a second length of tubing (18) is wound around the
15 wheel/cylinder part (11); that a first free end part (7) and a second free end part (8) are positioned exteriorly of the housing, and that said turnable first plate (10) comprises a circular plate/wheel (12) at its periphery where said second end part is conveyed around said return wheel (12) associated with the turnable unit and the turnable wheel/cylinder part (11).

20

9. A method according to claim 8; **characterised in** that tubing situated around the axle (4) is transferred to the turnable unit (6) and conversely during adjustment/unwinding of the length of the tubing.

25

10. A method according to any one of claims 8-9, **characterised in** that the tubing is wound about the axle in a first direction and wound around parts of the turnable unit in a second direction opposite the first direction.

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11. Use of an apparatus according any one of claims 1-7 for exercising the method according to any one of claims 8-10.

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12. Use of an apparatus according to any one of claims 1-7 for an infusion kit/infusion pump.

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